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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,553	08/14/2003	Wouter Cornelis Puijk	2183-6064US	3138

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EXAMINER

LUM, LEON YUN BON

ART UNIT PAPER NUMBER

1641

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/642,553	<b>Applicant(s)</b> PUIJK ET AL.	
	<b>Examiner</b> Leon Y. Lum	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

1. The amendment filed May 9, 2006 is acknowledged and has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al (US 5,807,522).

Brown et al teach a microarray (i.e. micro-array support) with discrete regions (i.e. surface patches) having immobilized reagents (i.e. first member binding molecules on spatially addressable spots), wherein the regions are hydrophilic regions surrounded by a hydrophobic grid pattern on the support surface (i.e. hydrophilic surface patches interspersed on hydrophobic surface areas). See column 8, lines 39-41; column 9, lines 31-45; and Figure 3. In addition, Brown et al teach that a multi-cell array can have 1mm x 1mm wells and droplets can have a volume of more than 100 nL (i.e. patches are smaller in at least one or two dimensions than the size of the circumference of the positioned droplets or spots). See column 8, lines 29-42; column 11, lines 52-61; and Figure 9.

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Furthermore, it is noted that the limitation "said support being provided with positioned droplets or spots of the first member molecules, wherein the patches are smaller in at least one or two dimensions than the size of the circumference of the positioned droplets or spots" (lines 8-11), is considered to be an intended use of the micro-array support. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In regards to claim 3, Brown et al teach that the hydrophobic regions can comprise polystyrene. See column 7, lines 47-54.

In regards to claim 5, Brown et al teach that each distinct biomolecule is disposed at a separate, defined position on the microarray (i.e. library of first member binding molecules). See column 4, lines 16-23 and lines 38-44.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al (US 5,807,522) in view of Drumheller (US 5,874,165).

Brown et al reference has been disclosed above, but fails to teach that the hydrophilic material comprises polyacrylic acid.

Drumheller reference teaches a support member comprising a hydrophobic polymeric support of polypropylene and 1<sup>st</sup> and 2<sup>nd</sup> layers of hydrophilic polyacrylic acid, in order to provide layers of chemically stable hydrophilic polymers to stably immobilize

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bioactive species. See column 10, lines 47-51; column 11, lines 14-19 and 61-66; column 12, lines 1-2; and column 14, lines 51-54. Drumheller also teaches that the bioactive species can include antibodies. See column 16, line 26.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Brown et al, with a support member comprising a hydrophobic polymeric support of polypropylene and 1<sup>st</sup> and 2<sup>nd</sup> layers of hydrophilic polyacrylic acid, as taught by Drumheller, in order to provide layers of chemically stable hydrophilic polymers to stably immobilize bioactive species. The polyacrylic acid of Drumheller has the advantage of preventing the loss of immobilized biomolecules, thereby providing motivation to substitute the polyacrylic acid for the hydrophilic material of Brown et al. In addition, one of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including hydrophilic polyacrylic acid, as taught by Drumheller, in the apparatus of Brown et al, since Brown et al teach hydrophilic spots on polystyrene substrates, and the polyacrylic acid of Drumheller is capable of being supported by polystyrene material.

### ***Response to Arguments***

8. On pages 7-9 of the Remarks, filed May 9, 2006, Applicants argue that Brown et al do not teach a support being provided with positioned droplets or spots of the first member molecules, wherein the patches are smaller in at least one or two dimensions than the size of the circumference of the positioned droplets or spots. Applicants point

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to column 12, lines 61-67 as supporting their argument, the citation stating that "defined-volume samples can be placed in each well without risk of cross-contamination with sample material in adjacent cells".

Applicants' arguments have been fully considered, but are not persuasive for at least two reasons. The first reason is that the limitation is considered to be an intended use of the claimed invention. Since the instant claims clearly indicate that the invention is an apparatus (i.e. micro-array support), recitation of method steps must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The application of droplets greater than a dimension of the patches, as claimed, does not necessarily produce a different microarray from that disclosed by Brown et al. Both microarrays comprise regions with binding probes arranged in separate, distinct regions on a substrate. There are numerous techniques known to one skilled in the art to produce microarrays, including various ways of spotting as described in the specification and in Brown et al. However, the end result for the different techniques is the same microarray with spatially addressable spots on a substrate. The microarray of Brown et al is no different from the micro-array support as claimed. For at least this first reason, Applicants' arguments are not persuasive.

The second reason is that Brown et al actually teaches droplets that are greater in circumference than at least one dimension of a single well in a multi-cell array, as described in the rejection supra. A 100 nL volume droplet, assuming spherical dimensions, has a radius of 6.16 mm, which corresponds to a circumference of 38.68

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mm. Since each well can have a length and width that are each 1 mm, Brown et al clearly teaches the claimed limitation.

Applicants' arguments are therefore not found to be persuasive and the rejections applied in the previous Office Action are maintained.

### ***Conclusion***

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.



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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner  
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